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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A-156736		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEAA16)	
International application No. PCT/B 03/02446	International filing date (day/month/year) 04.06.2003	Priority date (day/month/year) 10.06.2002	
International Patent Classification (IPC) or both national classification and IPC A61K9/00			
Applicant LABORATORIOS VITA, S. A.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 5 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand  19.12.2003		Date of completion of this report  23.09.2004	
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Villa Riva, A  Telephone No. +49 89 2399-8404 	



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/B 03/02446**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1, 2, 5-10, 12-24	as originally filed
3, 4, 11	received on 29.04.2004 with letter of 26.04.2004

**Claims, Numbers**

12 (part), 13, 14	as originally filed
1-11, 12 (part)	received on 29.04.2004 with letter of 26.04.2004

**Drawings, Sheets**

1/1	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-14
	No: Claims	
Inventive step (IS)	Yes: Claims	1-14
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

**see separate sheet**



## **Section V**

Reference is made to the following documents:

D1 - WO0112161, disclosing fast disintegrating tablets

D2 - NILSSON P ET AL: "PHYSICO-CHEMICAL ASPECTS OF DRUG RELEASE V. THE IMPORTANCE OF SURFACE COVERAGE AND COMPACTION ON DRUG DISSOLUTION FROM ORDERED MIXTURES" INTERNATIONAL JOURNAL OF PHARMACEUTICS (AMSTERDAM), vol. 45, no. 1-2, 1988, pages 111-122

disclosing drug release in quick disintegrating tablets as a function of the choice of excipients, surface and compaction;

D3 - MATTSSON S ET AL: "Formulation of high tensile strength rapidly disintegrating tablets: Evaluation of the effect of some binder properties" S.T.P. PHARMA SCIENCES 2001 FRANCE, vol. 11, no. 3, 2001, pages 211-220, disclosing ternary mixtures with compound, microcrystalline cellulose and superdisintegrant

D4 - US5904937, disclosing taste masked oral administration forms with microcrystalline cellulose,

D5 - US5686107, disclosing tablets with improved texture and taste

Although some of the cited prior art documents disclose oral preparations with the same ingredients, none of them shows the same ratios. Insofar the subject-matter of present claims 1-14 can be considered novel as required by the PCT Art. 33(1) and (2).

D1, which is the closest prior art, discloses the same combination of ingredients in claim 14 (at least from a qualitative point of view) as in present claim 1; the difference is that claim 14 is silent about the amounts of said ingredients. It is also silent on the point whether mannitol is spray-dried or prepared according to another technique.

Therefore, it would not be considered obvious for the skilled person to choose spray-dried mannitol or the ratios of claim 1; the presence of an inventive step can be acknowledged under Art. 33(1) and (3) PCT.